DRUG ENFORCEMENT ADMINISTRATION'S REGULATION OF MEDICINE

HEARING

BEFORE THE

SUBCOMMITTEE ON CRIME, TERRORISM, AND HOMELAND SECURITY

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PREPARED STATEMENT OF JOSEPH T. RANNAZZISI

Written Statement of

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July 12, 2007

Introduction

Chairman Scott, Ranking Member Forbes, and distinguished members of the House of Representatives Judiciary Committee, Subcommittee on Crime, Terrorism and Homeland Security, thank you for the opportunity to appear today and discuss and clarify any misapprehensions the Subcommittee may have regarding the role the Drug Enforcement Administration (DEA) plays in enforcing the Combat Methamphetamine Epidemic Act, upholding the Supreme Court decision *Ashcroft vs. Raich*, supporting cannabis research, and the responsibilities doctors in prescribing scheduled medications.

The Investigation of Methamphetamine Precursor Distribution

Methamphetamine is unique from other illicit drugs of abuse in that it is an easy to make synthetic drug and its precursor chemicals have historically been easy to obtain and inexpensive to purchase. These factors have contributed to methamphetamine's rapid sweep across our nation. In March 2006, reacting to the devastating impact that the illicit manufacture of methamphetamine was having on our nation, Congress enacted the Combat Methamphetamine Epidemic Act of 2005 (Title VII of the USA PATRIOT Improvement and Reauthorization Act of 2005, P.L. 109-177) or CMEA. Among other things, the Act established a system to monitor and regulate the importation, production, and retail sales of non-prescription ephedrine, pseudoephedrine, and phenylpropanolamine products - common ingredients found in over-the-counter cough, cold, and allergy products. These chemicals and drugs were included in CMEA because they are key precursors used in the illicit manufacture of methamphetamine or amphetamine. This legislation provided law enforcement and regulators with tools invaluable to the containment of the drugs' production.

As a result of the CMEA, the ability of pseudoephedrine to be sold on the spot market was effectively taken away. These transactions, which were not regulated under prior law, are now treated as new imports or exports and, therefore, subject to 15 day advance notification during which the DEA verifies the legitimacy of each transaction. In addition, the Department of Justice now has the authority to establish production and import quotas for ephedrine, pseudoephedrine, and phenylpropanolamine. These quotas will allow for greater control of precursors that are imported into the United States.

Retail provisions of the CMEA became effective in September 2006 and include self-certification, employee training, product packaging and placement requirements, sales logbooks, and daily and 30-day sales/purchase limits. In order to purchase products containing ephedrine, pseudoephedrine, and phenylpropanolamine, an individual must now show identification and sign a log book at sales locations. Law enforcement is able to monitor these log books in order to identify any person purchasing more than 9 grams within a 30-day period. CMEA also created a national database of self-certification records available to state and local law enforcement agencies to document those retail sales locations that have complied with the requirements of this law. As a testament to the effectiveness of the CMEA (and similar predecessor laws passed by the states), DEA statistics show a 58% decrease in the number of methamphetamine laboratories in 2006 from the previous year.

Additional CMEA provisions include: requiring DEA to conduct an assessment of the annual need of ephedrine, pseudoephedrine, and phenylpropanolamine, establishing production and import limits, requiring DEA be noticed of transfers following importation or exportation of methamphetamine precursor chemicals, and removing previously established sales thresholds, among others.

DEA is committed to keeping our communities safe from the dangers of methamphetamine production and abuse. Preventing the use of these chemicals in clandestine methamphetamine labs and via enforcement of the CMEA is an important element in that effort.

Investigations of Physicians Who Over-Prescribe Scheduled Drugs

The abuse of prescription drugs is a serious and growing health problem in this country. According to the 2005 National Survey on Drug Use and Health, there were more than 6 4 million current non-medical users of psychotherapeutic drugs in the United States - more than the number of Americans abusing cocaine, heroin, hallucinogens, and inhalants, combined. If we look at the people who are just starting out as new drug users, prescription drugs have overtaken marijuana and cocaine as the gateway drug of choice.

One of the goals set forth in this Administration's *2006 Synthetic Drug Control Strategy* is to reduce the abuse, or non-medical use, of prescription drugs by 15 percent over the next three years. Consistent with that end, a primary role of the DEA is to prevent the diversion of pharmaceutical controlled substances while ensuring an adequate supply for legitimate medical and scientific needs.

Diversion of legitimate controlled substances occurs from a number of sources, including, the Internet, pharmacy theft, doctor shopping, prescription forgery, and other means. Unfortunately, a small number of unscrupulous doctors are also illegally supplying those drugs. Although there are very few of them, they can cause tremendous damage. One such doctor in Panama City, Florida, was diverting so many OxyContin pills to abusers and traffickers that after the DEA arrested him, the street price of

OxyContin nearly doubled in the area because of the significantly diminished availability of the drug.

In 2006, there were approximately 750,000 medical doctors and doctors of osteopathic medicine registered with DEA. In any given year, including this past year, less than one in every ten thousand physicians in the United States loses his controlled substance registration based on a DEA investigation for improper prescribing—that is less than .01 percent of all physicians. And far fewer of those physicians are criminally prosecuted for improper prescribing.

The longstanding requirement under the law that physicians may prescribe controlled substances only for legitimate medical purposes in the usual course of professional practice should in no way interfere with the legitimate practice of medicine or cause any physician to be reluctant to provide legitimate treatment. And the DEA's responsibility to enforce the law does not diminish our firm commitment to the balanced policy of promoting pain relief and preventing the abuse of pain medications. To help physicians meet the challenge of ensuring that people who medically need drugs get them, and that those who are diverting them don't, the DEA has developed several initiatives since last fall.

On September 6, 2006, we published in the Federal Register *Dispensing Controlled Substances for the Treatment of Pain*, a policy statement that reiterated the requirements of the Controlled Substances Act and the physician's long-standing responsibility to take reasonable steps to prevent diversion. The DEA also published a Notice of Proposed Rulemaking, which proposes to amend the DEA regulations to permit doctors to issue multiple Schedule II prescriptions during a single office visit, allowing patients to receive up to a 90-day supply of controlled substances according to the fill date that the doctor gives the pharmacist.

The DEA also launched a new section on its website to provide everyone with the facts on investigations against doctors who violate federal drug laws. It's called "Cases Against Doctors." So far, DEA has had more than 80,000 hits to the site. DEA created this site to provide the public with information about the scope of violations that cause DEA to investigate doctors.

In addition, the DEA also updated (and posted on its website) its Practitioner's Manual to aid doctors with their responsibility to take reasonable steps to prevent diversion and abuse. Before it finalized the Practitioner's Manual, the DEA asked a number of doctors to review its updates to the earlier 1990 edition, and they found the new edition helpful in understanding their legal obligations in prescribing drugs.

The DEA agrees that doctors can and should prescribe controlled substances under legitimate medical standards to treat patients in pain. The DEA knows that doctors overwhelmingly agree with what Congress mandates it do: enforce our nation's laws to ensure drugs are used only for the health and welfare of the public.

Cannabis Research

Approval to conduct clinical research involving Schedule I substances in the United States is a joint process involving both the DEA and the Food and Drug Administration (FDA). Clinical studies of a substance for use as a drug must be performed by well qualified applicants who meet the most rigorous of standards in order to conduct bona fide research.

Following the procedures described in Title 21 of the Code of Federal Regulations, new applicants submit their applications to the DEA with research protocols and individual qualifications (typically a resume or curriculum vitae). The DEA is responsible for evaluating whether effective measures to adequately safeguard against diversion are in place as well as assessing factors relating to public interest (See 21 U.S.C. 811(b)). After a preliminary review to ensure completeness of the application and accompanying material, the application package is sent to the Controlled Substances Staff of the FDA and the DEA field office in the area of the proposed research. FDA's role is to determine the qualifications and competency of the applicant, as well as the merits of the protocol. The DEA field office conducts an on-site, pre-registrant investigation, including a personal interview with the applicant, to ensure that security is adequate to prevent diversion or abuse of the controlled substance.

Upon receipt of favorable reports from both the FDA and the DEA field office, a certificate of registration is issued to the researcher. No research with a Schedule I controlled substance can be initiated until the DEA approves the application and a Schedule I research registration is assigned. The DEA has never denied an application to a researcher when FDA has determined that the qualifications and merits of the applicant (as well as of the research proposed) are acceptable, and that adequate security measures are in place.

At present 110 researchers are registered to perform studies within the drug category which includes marijuana, marijuana extracts and non-tetrahydrocannabinol marijuana derivatives that exist in the plant, such as cannabidiol and cannabinol. These studies include evaluation of abuse potential, physical/psychological effects, adverse effects, therapeutic potential, and detection. Nineteen researchers are currently approved to conduct research with smoked marijuana on human subjects.

Enforcing Federal Law in Light of Claims that Marijuana is "Medicine"

Marijuana is a Schedule I substance under Title 21 of the United States Code. As defined by law, a Schedule I substance is one that has *no currently accepted medical use in treatment in the United States*, no accepted safety for use under medical supervision and a high potential for abuse. Along with marijuana, other Schedule I controlled substances include heroin and LSD.

Under the Controlled Substances Act (CSA), DEA is required to act in consultation with the FDA in determining whether a controlled substance has a currently accepted medical use. Under the Federal Food, Drug, and Cosmetic Act (FDCA), it is unlawful to market a new drug in the United States unless FDA approves the drug as being both safe and effective for the treatment of disease or condition. To date, FDA has not found marijuana to be safe and effective for the treatment of any disease or condition. Given the absence of sound scientific evidence establishing that marijuana can be used safely and effectively as medicine, it remains a Schedule I controlled substance under the CSA and illegal under the FDCA to market as a drug. Reviews of the scientific evidence can be triggered by an application to the FDA for approval of marketing of a new drug, or for the new formulation of an existing drug. Reviews can also be triggered by rescheduling petition requests filed with the DEA.

DEA's efforts to enforce Federal law surrounding the possession and trafficking of marijuana have been hampered by the passage of laws in several states which inhibit State and local law enforcement from acting against individuals and organizations selling marijuana under the pretence that it has medicinal value.

Law enforcement has seen a growing list of ailments used by dealers, patients and physicians to justify smoking marijuana. It has become so exhaustive that anyone could claim "a medical need". That list includes ADD, headaches, arthritis, PMS, IBS, hepatitis, renal failure, hypertension, anxiety, depression, post-traumatic stress disorder, insomnia, paranoia, bipolar affective disorder, alcoholism, cocaine and amphetamine addiction, epilepsy, bronchitis, emphysema, osteoporosis, degenerative disc disease, polio, ulcers, stuttering, seizures, color blindness and various types of pain. In a *USA Today* article on March 8, 2007, Scott Imler, who co-wrote the California "medical" marijuana initiative in 1995 said, "What we set out to do was put something in the statutes that said medicine was a defense in case they got arrested using marijuana for medical reasons. What we got was a whole different thing, a big new industry." Imler added "I was pretty naïve, I thought people would act in good faith." Anecdotal information and data have suggested in Los Angeles the significant likelihood that the marijuana as medicine dispensaries affect crime in adjacent communities.

The authority of DEA to investigate those growing, selling, and possessing marijuana, irrespective of State law, was confirmed by recent rulings by the Supreme Court. In *United States v. Oakland Cannabis Buyers' Cooperative*, the Supreme Court held that the Controlled Substances Act contains no exception permitting the distribution of marijuana on the basis of "medical necessity." In *Gonzales v. Raich*, the Court stated that Congress's Commerce Clause authority includes the power to prohibit the intrastate and noncommercial manufacture and possession of marijuana for claimed medical purposes pursuant to state law and concluded that, "Congress had a rational basis for believing that failure to regulate the intrastate manufacture and possession of marijuana would leave a gaping hole in the Controlled Substances Act." These two cases made clear that Federal law prohibiting the manufacture, distribution, and possession of marijuana applies regardless of whether the person engaging in such activity claims to have a "medical necessity," claims to be acting in accordance with state law, or claims to

be acting in a wholly intrastate manner. Thus, DEA remains constitutionally obligated to enforce the Controlled Substances Act in all circumstances.

The DEA's role is one of enforcement. It is, after all, our middle name. We will continue to enforce the law as it stands and to investigate, indict, and arrest those who use the color of state law to possess and sell marijuana.

Conclusion

The Drug Enforcement Administration is a single mission agency. Our role is to enforce the provisions of the Controlled Substances Act, which is considered by Congress to be in the best interests of the people of this nation. The DEA does not discriminate in the application of the law, nor does it interpret the law's intent, a function left appropriately to the courts. The DEA applies the law to law breakers. Among other things, it does so through the Combat Methamphetamine Epidemic Act to prevent the spread of the bill's namesake drug, through the carefully application of its regulatory obligations or by investigating those who would use the color of state law to traffic in marijuana.

I thank you for the opportunity to testify here today, and would welcome any questions the Subcommittee might have.

U.S. Department of Justice

Office of Legislative Affairs

Office of the Assistant Attorney General

Washington, D.C. 20530

March 7, 2008

The Honorable John Conyers, Jr.
Chairman
Committee on the Judiciary
United States House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Please find enclosed a response to questions arising from the appearance of Drug Enforcement Administration Deputy Assistant Administrator Joseph Rannazzisi before the Committee on July 12, 2007, at a hearing entitled "The Drug Enforcement Administration's Regulation of Medicine".

We hope that this information is of assistance to the Committee. Please do not hesitate to call upon us if we may be of additional assistance. The Office of Management and Budget has advised us that from the perspective of the Administration's program, there is no objection to submission of this letter.

Sincerely,

Brian A. Benczkowski
Principal Deputy Assistant Attorney General

Cc: The Honorable Lamar S. Smith
Ranking Member

"The Drug Enforcement Administration's Regulation of Medicine"

July 12, 2007

Questions for the Hearing Record
for
Joseph T. Rannazzisi
Deputy Assistant Administrator
Office of Diversion Control
Drug Enforcement Administration

1. **The Drug Enforcement Administration and the Food and Drug Administration are both involved in the approval of cannabis research (and researchers) prior to the issuance by DEA of a Schedule I registration. There seemed to be some confusion as to what this process is. Please describe in detail the process a would-be researcher must go through before DEA issues the registration and explain at each step what would prohibit the process from continuing.**

RESPONSE:

The Controlled Substances Act (CSA) allows for bona fide research to be conducted on any schedule I controlled substance provided the researcher has obtained a registration from DEA authorizing such activity. The statutory criteria for obtaining a registration, including the role of the Secretary of Health and Human Services (HHS), are set forth in 21 U.S.C. § 823 (f). Among other things, the statute requires the researcher to submit a research protocol. The required contents of the research protocol are specified in the DEA regulations (21 C.F.R. § 1301.18). A detailed description of the process by which DEA acts on applications for registration with schedule I controlled substances is also set forth in the DEA regulations (21 C.F.R. § 1301.32). In sum, the Secretary of HHS is responsible for evaluating the qualifications and competency of the researcher and the merits of the research protocol, and DEA is responsible for ensuring that the researcher will provide adequate controls against diversion and otherwise comply with the CSA and DEA regulations. An application may be denied if: the applicant fails to meet any of the foregoing requirements; the Secretary for HHS finds the qualifications and competency of the researcher, or the merits of the research protocol, to be lacking; or DEA determines that the researcher has failed to demonstrate that he/she will maintain effective control against diversion. If DEA seeks to deny the application for any reason, it must serve the applicant with an Order to Show Cause, affording the applicant the opportunity for a hearing in accordance with the Administrative Procedure Act, 21 U.S.C. § 824(c).

2. **During the hearing, testimony was offered that indicated investigations of pain management doctors and other doctors by DEA have caused concern that physicians who practice in this area of medicine are being targeted despite the service they provide to a number of pain sufferers. Does DEA believe this characterization is correct, and what is the process DEA uses to identify and**

investigate doctors whose practices dispense large quantities of opioids and other pain relievers?

RESPONSE:

The characterization that the DEA "targets" physicians simply because they practice pain management is false and does disservice to those doctors acting professionally. The overwhelming majority of prescribing done by physicians in America is conducted responsibly. Often it is these doctors and pharmacists who dispense the medication who are the first to alert law enforcement to potential prescription problems. However, the small number of physicians who over prescribe controlled substances—carelessly at best, knowingly at worst—help supply America's second most widespread drug addiction problem. Although the problem exists, the number of physicians and pharmacists responsible for this problem is a very small fraction of those registered with DEA to prescribe and dispense controlled substances in the United States.

DEA's obligation under the law and to the public is to ensure that pharmaceutical controlled substances are prescribed and dispensed only for legitimate medical purposes. By carrying out this obligation, DEA strives to minimize the diversion of pharmaceutical controlled substances for abuse while ensuring that such medications are fully available to patients in accordance with the sound medical judgments of their physicians. In this manner, DEA is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to these drugs.

DEA investigates complaints against registrants for potential criminal and administrative violations. Sources of those complaints include state medical boards, patients, pharmacists, or employees of the doctor. If an investigation reveals possible criminal or civil violations of the CSA, DEA refers the matter to the United States Attorney's Office for further review and whatever action that office deems appropriate. In addition, if DEA determines that there is a statutory basis under the CSA to revoke a practitioner's registration, the agency has the discretion to initiate such proceedings. If DEA seeks to revoke a practitioner's registration for any reason, it must serve him/her with an Order to Show Cause, affording the applicant the opportunity for a hearing in accordance with the Administrative Procedure Act, 21 U.S.C. 824(c).

DEA is also charged with registering companies, pharmacies, and physicians who handle or dispense controlled substances. Those who are registered to conduct this activity must meet and continue to meet various regulations that are set forth in the Code of Federal Regulations.

DEA continues to work closely with the state medical boards and their affiliated organizations to alleviate any possible remaining misconceptions about how DEA carries out its administrative duties under the CSA. As stated in the 2006 *Synthetic Drug Control Strategy,* the Administration is committed to balancing the need for prevention, education, and enforcement with the need for legitimate access to pharmaceutical controlled substances.

3. **During the hearing, statements were made that it was inappropriate for DEA to investigate doctors, and that doing so was the equivalent of 'regulating medicine.'**

Why does the DEA investigate and engage in the prosecution of pain management practitioners and others in the medical profession, when established state medical boards exist to monitor and punish ethical violations of medical practice?

RESPONSE:

Please note that DEA addressed this issue in its September 6, 2006, Policy Statement published in the Federal Register. As stated therein:

> DEA is the agency within the Department of Justice responsible for carrying out the functions assigned to the Attorney General under the CSA. These functions include enforcing and administering the CSA provisions governing the prescribing, administering, and dispensing of controlled substances. Thus, the scope of DEA's authority is delineated by the extent to which Congress itself regulated controlled substances through the enactment of the CSA and assigned certain functions under the Act to the Attorney General.
>
> While the CSA is one component of the overall regulation of the practice of medicine in the United States, it bears emphasis that the CSA does not regulate the practice of medicine as a whole. Therefore, although DEA is the agency responsible for administering the CSA, DEA does not act as the federal equivalent of a state medical board overseeing the general practice of medicine. State laws and State licensing bodies (such as medical licensing boards) collectively regulate the practice of medicine. In contrast, the scope of the CSA (and therefore role of DEA) is much narrower. The CSA regulates only the segment of medical practice involving the use of controlled substances, and DEA is correspondingly responsible for ensuring that controlled substances are used in compliance with federal law.
>
> In particular, DEA's role under the CSA is to ensure that controlled substances are prescribed, administered, and dispensed only for legitimate medical purposes by DEA-registered practitioners acting in the usual course of professional practice and otherwise in accordance with the CSA and DEA regulations. Each state also has its own laws (administered by state agencies) requiring that a prescription for a controlled substance be issued only for a legitimate medical purpose by state-licensed practitioners acting in the usual course of professional practice.
>
> There is nothing new in this arrangement of responsibilities between the federal and state governments. For more than 90 years (starting with the Harrison Narcotic Act of 1914, which was superseded by the CSA in 1970) federal law has placed certain restrictions on the medical use of federally controlled substances while, at the same time, the states have regulated the practice of medicine generally. In this respect, there has long been a certain amount of overlap between the federal and state oversight of controlled substances.

Beginning in the 1930s and through to the present, states have adopted uniform controlled substance laws that were designed to promote standards that are consistent from state to state and in harmony with federal law. One such standard that has always been a fundamental part of these uniform state laws is the requirement that controlled substances be dispensed only for legitimate medical purpose by a practitioner acting in the usual course of professional practice – a requirement first articulated in the Harrison Narcotic Act. Accordingly, it has been the case for more than 70 years that a practitioner, who dispenses controlled substauces for other than a legitimate medical purpose, or outside the usual course of professional practice, is subject to legal liability under both state and federal law.

4. **On May 15, DEA Administrative Law Judge Mary Ellen Bittner formally transmitted her recommendation to DEA Depnty Administrator Michele Leonhart in which she found that it is "in the public interest" to end the federal monopoly on the supply of marijuana that can be used in FDA-approved research, held by the National Institute on Drug Abuse (NIDA). Following nine days of hearings, testimony, and evidence from both sides, including from researchers who reported that the government denied their reqnests for marijuana for use in FDA-approved research protocols, Judge Bittner concluded that, "NIDA's system for evaluating requests for marijuana has resulted in some researchers who hold DEA registrations and requisite approval from [HHS and FDA] being unable to conduct their research because NIDA has refused to provide them with marijuana. I, therefore, find that the existing supply is not adequate." She added, "Respondent's registration to cultivate marijuana would be in the public interest."**

Despite this endorsement by the one neutral arbiter assigned to examine the case and despite the fact that it has been more than six years since the University of Massachusetts initially filed its application, the DEA has yet to grant the license in accordance with the recommendation. With these facts in mind, I would like to know how long it usually takes the DEA to act on a recommendation from an administrative law judge. Could you please provide me with a list of all recommendations made by administrative law judges in the DEA since January 20, 2001, along with the dates on which they were transmitted to final decision-makers at the DEA and the dates on which the recommendations were officially either followed or rejected through a final decision on the matter?

Also, when can we anticipate a decision in this case? If the decision can be anticipated to require more time than the average time required in the reply to the first question, please state the reason. In addition, can you give us a commitment that the decision will be made during this Administration?

RESPONSE:

Please see attached chart.

5. **In his written testimony of Joseph T. Rannazzisi, DEA Deputy Assistant Administrator, Office of Diversion Control, stated, "Nineteen researchers are currently approved to conduct research with smoked marijuana on human subjects." Could you please provide the name and affiliation of each of these researchers, along with a short description of the research they are currently conducting?**

RESPONSE:

Please note that the information requested in this question includes personally identifiable records maintained by DEA, which are protected by the Privacy Act. DEA is releasing this information to the subcommittee in response to this question under the exception for disclosures to Congress set forth in 5 U.S.C. § 552a (b)(9).

- Donald Abrams, M.D. (University of California -San Francisco; CMCR*)
- Mark Agius, M.D. (University of California-Davis; CMCR*)
- Robert Block, Ph.D. (University of Iowa)
- Louis Cantilena, M.D., Ph.D. (Uniformed Services University of Health Services)
- Jody Corey-Bloom, M.D., Ph.D. (University of California-San Diego; CMCR*)
- Ronald Ellis, M.D., Ph.D. (University of California-San Diego; CMCR*)
- Richard Foltin, Ph.D. (Columbia University)
- Alan Gevins, Ph.D. (SAM Technology Inc.)
- Mark Greenwald, Ph.D. (Wayne State University)
- Kent Hutchison, Ph.D. (University of Colorado)
- Thomas Kelly, Ph.D. (University of Kentucky)
- Scott Lane, Ph.D. (University of Texas-Houston)
- Anthony Liguori, Ph.D. (Wake Forest School of Medicine)
- Scott Lukas, Ph.D. (McLean Hospital)
- Jane Metrick, Ph.D. (Brown University)
- Godfrey Pearlson, M.D. (Institute of Living)
- Donald Tashkin, M.D. (University of California Los Angeles)
- Mark Wallace, M.D. (University of California -San Diego; CMCR*)
- Barth Wilsey, M.D. (Department of Veteran Affairs; CMCR*)

Of the 19 researchers listed above, 13 are conducting NIDA-funded drug abuse research. An additional 6 are affiliated with the *Center for Medicinal Cannabis Research (CMCR) from the University of California and are investigating the use of smoked marijuana in six approved studies.

The CMCR studies are evaluating the use of cannabis for the treatment of: HIV-related peripheral neuropathy; cancer pain; spasticity/tremor in MS patients; and chemotherapy-induced delayed nausea. These studies represent the breadth and scope of research using marijuana to study the potential therapeutic effectiveness of marijuana's active ingredients.

Policy on Letters of Non-Objection

The committee has heard from a number of companies that DEA has virtually stopped issuing Letters of Non-Objection, or LONOs – since February of 2006. I would greatly appreciate it if you could help me understand the current LONO policy in greater detail, as well as DEA's rationale behind the decision to implement this policy.

6. **How many LONO requests did DEA approve and deny in 2004, 2005, and in 2006 until February 28, and what were the reasons for denial in cases where DEA rejected a LONO application?**

RESPONSE:

During the time period in question, the DEA received approximately 1,069 requests for LONOs. Of that total, 41 (4%) were withdrawn by the importer after being notified that the LONO would not be issued. The breakdown by year is as follows: 2004, 519 LONO requests, 6 (2%) withdrawn; 2005, 483 LONO requests, 32 (7%) withdrawn; 2006 (through Feb. 28), 67 LONO requests, 3 (4.5%) withdrawn. LONOs not being issued were based on the reasonable belief that the products will be diverted for use in the clandestine production of illicit drugs.

If there is reason to believe that the chemicals will be diverted into illicit channels, DEA sends the importer a 3-Option letter. This letter explains that a particular shipment may be diverted (21 U.S.C. § 971) and then gives the importer three options. The first option for the importer is to voluntarily withdraw the DEA-486; the second is to do nothing and in 30 days, it will automatically be withdrawn or the last option is to request a hearing. The letter further explains the regulatory process and indicates that if the third option is chosen, then the shipment will be suspended and the importer has a right to a hearing. All importers are afforded the opportunity to participate in the regulatory system.

7. **How many LONO requests are currently pending before DEA? I would appreciate knowing when the LONO requests were submitted. How many of these LONO requests have been pending for more than 6 months without a response from DEA?**

RESPONSE:

As of August 24, 2007, there were eight (8) pending DEA 486 (LONO) requests. There are no DEA 486s pending for more than six months. When a request is received from the importer, the request is usually processed within approximately two weeks. This time is dependent upon how quickly the down stream customers reply to DEA's requests for information in order to conduct the verification process. The number of pending LONO requests changes daily as new ones arrive and are processed.

8. **Are there any companies who have submitted a LONO application for whom a LONO has been approved? It is my understanding that Wyeth and Bayer have both received such approvals.**

RESPONSE:

Please refer to the numbers provided in the previous responses. Companies do not submit a "LONO application". Companies do, however, submit a form DEA-486, which is an Import/Export declaration form sent in to DEA by the importer. That form constitutes a request for the issuance of a LONO if the export is from a country that will not release shipments of ephedrine and pseudoephedrine unless the United State Government issues a LONO. Generally speaking, imports are approved unless cancelled by the importer or there is reasonable cause to believe the imported chemical will be diverted to the clandestine production of drugs. LONO requests from any importer of ephedrine and pseudoephedrine would have been approved unless there was reasonable cause to believe that the chemicals would be diverted to the clandestine manufacture of methamphetamine. Unless a LONO request is cancelled by the importer, all LONOs have either been approved or DEA has issued an order to suspend the shipment. Importers whose shipments are suspended are entitled to a hearing. However, LONOs are issued only to registered importers. Wyeth and Bayer are not registered with the DEA as importers of List I chemicals.

9. **Has DEA received and approved any LONO applications from companies who seek to import ephedrine or other List 1 chemicals used for prescription or related pharmaceutical uses?**

RESPONSE:

DEA has received form DEA-486s for List I chemicals where the ultimate end-use is for the manufacture of legitimate prescription drug products and they go through the same downstream customer verification process as the OTC manufacturers.

10. **What criteria does DEA currently employ to approve or reject a LONO request?**

RESPONSE:

Title 21 U.S.C. § 971(c) states that the Attorney General may order the suspension of any importation of a listed chemical on the ground that the chemical may be diverted to the clandestine manufacture of a controlled substance. Upon the receipt of a LONO request, the DEA conducts an investigation of the downstream distribution chain. If a determination is made that the product may be diverted, the LONO is not issued. If the request to import the List I chemical is not withdrawn by the importer, DEA issues an order suspending the proposed importation.

11. **We have heard that DEA does not intend to approve any LONO requests until the agency determines the "medical and scientific" necessity for List 1 chemicals, particularly ephedrine and pseudoephedrine? If so, why would the U.S. Food and**

Drug Administration's (FDA) determination of the medical necessity of ephedrine and other List 1 pharmaceuticals – as a condition of allowing them onto the market – not serve as sufficient evidence for DEA – especially in light of the apparent injury caused to responsible and law-abiding companies by the delay?

RESPONSE:

"Medical and scientific necessity" was not the terminology utilized by Congress in enacting 21 U.S.C. § 971(c). Therefore, such terminology is not utilized by DEA in implementing this provision. DEA is mandated by 21 U.S.C. § 952(a)(1) to authorize the importation of ephedrine and pseudoephedrine only in such amounts as are necessary to provide for medical, scientific, or other legitimate needs of the United States. Furthermore, this is also in accordance with a United Nations resolution that urges the calculation of valid licit use estimates for ephedrine and pseudoephedrine and allows for monitoring by the U.N. International Narcotics Control Board (INCB) to help keep imports and exports within these licit use estimates. Although a product may be approved as "safe and effective" by the FDA for a medical use, only the amount necessary to provide for the legitimate needs of the United States may be imported. DEA processes requests to import all controlled substances and listed chemicals thoroughly prior to deciding whether to send a LONO or deny the importation. DEA does not concede that any company has been injured by any alleged delay in this process.

The Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured domestically and/or imported into the United States to provide adequate supplies of each chemical for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. DEA obtained assistance from a private independent contractor, IMS Health Government Solutions, to develop estimates of the medical needs of the United States for both ephedrine and pseudoephedrine.

12. **What is DEA's statutory authority and substantive expertise to make medically-based determinations such as "medical and scientific" determinations of List 1 chemicals? Does DEA coordinate with other agencies such as the FDA or HHS in making those determinations?**

RESPONSE:

DEA's statutory authority rests in 21 U.S.C. §952. This statute prohibits the importation of controlled substances or ephedrine, pseudoephedrine, and phenylpropanolamine except in amounts "as the Attorney General finds to be necessary to provide for medical, scientific, or legitimate purposes". When making a scheduling recommendation, DEA coordinates with FDA/HHS for their expertise in evaluating a particular drug.

Since this question is similar in content to question 6, the response must by necessity repeat some of the answer to that question. The Assessment of Annual Needs represents those quantities of ephedrine, pseudoephedrine, and phenylpropanolamine which may be manufactured

domestically and/or imported into the United States to provide adequate supplies of each chemical for: the estimated medical, scientific, research, and industrial needs of the United States; lawful export requirements; and the establishment and maintenance of reserve stocks. DEA obtained assistance from a private independent contractor, IMS Health Government Solutions, to develop estimates of the medical needs of the United States for both ephedrine and pseudoephedrine.

13. If DEA has, in fact, adopted a policy of deferring decisions on LONO applications until a medical and scientific necessity of List 1 chemicals is determined, what provisions are being extended to lawful importers and distributors whose business and livelihood depend on the continued importation of raw materials?

RESPONSE:

DEA does not have a policy of deferring decisions on LONO requests based on medical and scientific necessity.

14. How many incidents have there been where Over-The-Counter (OTC) ephedrine combination products such as Primatene or Bronkaid have been found to be used in the manufacture of methamphetamine, and what percentage of the total methamphetamine supply in the U.S. does DEA believe comes from illicit diversion of these specific types of combination products?

RESPONSE:

An exact number of incidents where OTC pseudoephedrine and/or ephedrine combination products have been found in clandestine laboratories is not possible to ascertain. Clandestine laboratories are often found in various stages of production with the precursor chemicals in solution or finished product. Both combination and single entity OTC ephedrine and pseudoephedrine products are found at clandestine methamphetamine labs. It should be noted that traces of antihistamines or other residual ingredients are frequently encountered in methamphetamine samples taken at clandestine labs, indicating the diversion of OTC combination products.

As provided in testimony on July 12, 2007, brands found in 87 labs in 2006, included BDI, Blue Label, Mini Thins, Brochis, Mini Ephedrine, Double Action Ephedrine, Rapid Ephedrine, Fred's Private Label, Ephedrine Extra, Biotech, AM, BC Powder and Ultra Max Strength. Those are all off-brand, gray market, crypto-generic products.

Ephedrine Import Policy

The committee is concerned over the uncertainty of how import quotas pertaining to List 1 chemicals will be allocated amongst small importers. This lack of information and uncertainty about the supply of essential List 1 chemicals for their health products has disrupted short- and

long-term business operations. Importers and distributors are anxious to plan for their future distribution of product to potential customers, including chain drug stores.

In light of this uncertainty, please respond to the following questions:

15. What criteria will DEA use in making import quota allocations?

RESPONSE:

Registrants are required to submit a completed DEA Form 488, Application for Import Quota for Ephedrine, Pseudoephedrine, and Phenylpropanolamine, in order for DEA to establish an individual import quota. DEA will evaluate the information submitted on the application including data relating to purchases, sales, and inventory for the current and preceding two years. However, certain import quota requests might require additional information such as product development requirements or other requirements necessary to complete bona fide scientific research/clinical trials. DEA has expertise in processing these types of quota applications for manufacturers of controlled substances in Schedules I and II and will work with quota applicants to obtain the information necessary to process these types of quota requests.

16. When will proposed import allocations be made by DEA?

RESPONSE:

On July 10, 2007, the DEA published in the Federal Register, an Interim Final Rule with Request for Comment which implements the quota provisions envisioned by Congress when it passed the Combat Methamphetamine Epidemic Act (CMEA) in March 2006. Although the rule became effective immediately, DEA did not administer individual quotas to importers of these List I substances for imports required in 2007. Instead, DEA has been obtaining 2008 import applications which will be adjudicated after DEA publishes a final rule in the Federal Register establishing the 2008 Assessment of Annual Needs for each of these List I chemicals. The 2008 Assessment of Annual Needs was published in the Federal Register on December 27, 2007 (72 FR 73361).

On December 27, 2007, DEA issued individual import, manufacturing and procurement quotas to 38 applicants who had filed timely quota applications. DEA received exactly 100 complete applications in 2007 for 2008 quotas; approximately 40% were received in the month of December and currently remain under review. Three (3) of the sixteen (16) import quotas received in 2007 were issued on that day. Until a quota has been allocated to importers, it will not be permitted to handle any subject materials. DEA is not currently aware of any delays in this process. Looking forward, it is not anticipated that any delays, to the extent they become reality, will cause extended waiting periods.

17. Once import allocations are proposed, will DEA provide importers with an opportunity to submit comments and make recommendations for revisions in the import formula?

RESPONSE:

The assessment of annual needs (AAN) represents the total quantity of ephedrine, pseudoephedrine, and phenylpropanolamine determined to be necessary to be manufactured and imported during the calendar year. The DEA shall publish in the Federal Register a general notice of an assessment of annual needs for ephedrine, pseudoephedrine, and phenylpropanolamine. Any interested persons are permitted to file written comments on or objections to the proposed AAN within the designated comment period. After consideration of any comments or objections, the DEA shall issue and publish in the Federal Register the final order determining the AAN for the chemicals.

18. **Once import allocations are finalized, what process will DEA establish to allow importers to request modifications to the allocations based on production and sales data?**

RESPONSE:

Any person to whom an import qnota has been issued may at any time request an adjustment in their individual import quota. Applications for adjustments to an individual import quota which are received during the calendar year must be denied by DEA within 60 days of receiving a completed request for such adjustment, otherwise the request is deemed approved 21 U.S.C § 952(d) (21 C.F.R. § 1315.36).

Any persons to whom an individual import quota has been issued may, at any time during the calendar year, request an adjustment in their individual import quota by applying to the Administrator with a statement that establishes the basis for the adjustment.

Harassment of Small Business

The Committee is aware of specific instances of DEA investigators threatening to issue show cause letters simply for doing business with convenience stores, which the DEA has defined as the "gray market." Furthermore, and even more alarming, we are aware of small businesses being asked to surrender their List 1 chemical licenses without any evidence of wrongdoing.

An example of this policy and practice is contained in the transcript of an April 18, 2006 administrative hearing regarding a List 1 chemical distributor in Tennessee.

A DEA Investigator testified that it is DEA's policy to seek the license revocation of *any* List 1 chemical distributor who conducts business with the so-called gray market, even in the absence of any evidence of chemical diversion or violations of DEA regulations. During cross examination by counsel at the administrative hearing, Investigator Graham responded to the following questions:

> *Q. "...Is it your testimony that it's DEA policy to seek the revocation of any person or entities that is registered and sells in the gray market?"*

A. "Yes, sir."

Q. "Irrespective of whether they abide by the rules and regulations?"

A. "Yes, sir."

Q. "My question is, is it DEA policy to revoke the registrations of persons who are selling in the gray market, but comply with rules and regulations of the sale of List 1 chemicals?"

A. "...I would like to respond to your question. Generally, the answer is yes, but I must stress that the issue is what they are selling. Now when we talk about the nontraditional products into gray market establishments, yes, we seek those revocations."

Q. "Even when those persons or businesses follow the Code of Federal Regulations?"

A. "Yes, sir."

Due to these concerns, please respond to the following questions:

19. What is DEA's overall enforcement strategy in identifying and dismantling small toxic laboratories (STLs) that produce Methamphetamine?

RESPONSE:

Firstly, DEA regrets the Committee's use of the word 'harassment' in the title of this section of questions. In seeking answers, use of the word inherently assumes the Committee has already taken a position.

As a testament to the effectiveness of the Combat Methamphetamine Epidemic Act (CMEA) passed by Congress and strong state legislation, DEA statistics show a 41% decrease in the number of methamphetamine laboratories in 2006 from the previous year. This is 41% fewer laboratories that will expose children to hazardous chemicals, 41% fewer laboratories that state and local law enforcement officers will spend hours overseeing environmental clean-ups, and 41% fewer laboratories that state and local agencies will have to spend thousands of dollars in hazardous waste clean-ups. It is also 41% fewer labs producing a toxic drug that ruins American families and communities and weakens our productivity.

A logical means to eliminate the STLs is to choke off their sources for meth ingredients, mainly ephedrine and pseudoephedrine of the kind found in OTC cold remedy products. The recent significant reduction in the number of domestic small toxic labs and legislation restricting access to methamphetamine precursor chemicals has allowed DEA's Clan Lab Enforcement Teams to expand their efforts beyond dismantling methamphetamine labs. These teams can now

concentrate on identifying and targeting large-scale Mexican methamphetamine trafficking organizations. These teams use their lab expertise to trace chemicals, finished methamphetamine, and drug proceeds to drug trafficking organizations in the U.S. and Mexico. These teams also work to identify and dismantle U.S.-based methamphetamine transportation and distribution cells.

DEA is committed to keeping our communities safe from the dangers of methamphetamine production and abuse. Preventing the use of chemicals from being diverted to clandestine labs for use in the production of methamphetamine and enforcement of the CMEA are important elements in that effort.

20. What is DEA's current enforcement policy with regard to identifying precursors used in clandestine laboratories for the production of illicit methamphetamine?

RESPONSE:

DEA investigators are trained to pursue all leads, including backtracking of chemicals heading to or found at a clandestine lab site, chemical cache, or dumpsite.

21. Did the DEA Investigator at question here accurately describe DEA's enforcement policy during his testimony at the April 18, 2006, hearing, that DEA is seeking the revocation of any List I chemical registrant who is doing business with the gray market?

RESPONSE:

The Diversion Investigator testified truthfully, but mistakenly, based on his understanding of DEA's policies and procedures. In fact, DEA does not have a policy to revoke the registration of every distributor that sells scheduled listed chemical products to "gray market" outlets. The investigator's testimony would have been more precise if he testified that so-called gray market ephedrine and pseudoephedrine products deemed to be obtained and diverted for use in the illicit production of controlled substance are often found in gray market venues. This marketplace for non-traditional products is a known source for domestic methamphetamine production. Accordingly, distributors that sell gray market products to gray market outlets often present a significant risk of diversion of scheduled listed chemical products.

22. If DEA does have a policy of seeking the revocation of List I registrants that do business in the gray market, what is the policy specifically, and what is the statutory or regulatory basis for such policy?

RESPONSE:

DEA does not have such a policy.

23. How does DEA define the so-called "gray market?"

RESPONSE:

DEA knows by experience that a "gray market" exists wherein certain pseudoephedrine and ephedrine products are distributed only to non-traditional outlets for medications such as convenience stores and gas stations and from where they have a high incidence of diversion with little or no accountability as to their final uses. These "gray market" products are not sold in large discount stores, retail pharmacies, or grocery chains, where legitimate sales of therapeutic OTC drugs predominate. "Two-way" combination ephedrine and high strength single-entity pseudoephedrine products, which are "crypto-generic" in that they are manufactured by firms with no discernible market share or observable demand, are the primary products in this "gray market" industry. These products are rarely found in any retail store serving the traditional therapeutic market. Many distributors of these products distribute ephedrine to convenience stores, gas stations, and other "gray market" retailers in amounts that far exceed legitimate demand for therapeutic use.

Despite numerous public announcements and letters to distributors, DEA believes that many of the "gray market" retailers of these products have not self-certified under the provisions of the Combat Methamphetamine Epidemic Act and, therefore, have not come into compliance with the Act.

In the recent past, several cases have been adjudicated which resulted in decisions favoring the government. One such final rule, FR Doc 04-4127 [Federal Register: February 25, 2004 (Volume 69, Number 37)] [Notices] [Page 8682-8696], re: *Branex – Final Order – 02/25/04,* demonstrates the gray market principle.

24. Does DEA have any evidence that traditional convenience stores and small retail establishments are intentionally diverting List 1 chemicals into STLs? If so, what evidence exists?

RESPONSE:

According to DEA reports, convenience stores and gas stations in many states have, for years, continued to be the primary source for precursors being diverted to illicit methamphetamine laboratories.

During March 2001, DEA utilized an expert in the field of retail marketing and statistics to analyze national sales data for OTC, non-prescription drugs. Using official government and commercially available sales data, he was able to construct a model of the traditional market for pseudoephedrine in the retail sector. His study showed that over 90% of all sales of non-prescription drug products occurred in drug stores, grocery stores and large discount merchandisers. A very small percentage of such sales occurred in convenience stores, and many convenience stores do not sell any OTC drug products at all.

This expert analyzed expected sales of non-prescription drugs by convenience stores that sold such products and found that they constituted a very small portion of their total sales. The average small convenience store averages about $1,000,000 in gross sales. Health and beauty aids category (HABA) averages about 2-3% of gross sales. Cough and cold products, a subset of HABA, average about one-fourth of HABA sales. The expert calculated that single-entity pseudoephedrine sales were about 5% to 10% of cough and cold sales. Accordingly, the average small store could expect to sell monthly only about $0.00 to $40.00 worth of pseudoephedrine products. At an average markup of 40% over wholesale prices, this would translate to about 3 to 12 packages a month. He calculated that the potential for sales of combination ephedrine products was about only one-fourth of those pseudoephedrine sales levels.

DEA has observed through investigations that a number of "gray market" convenience stores and gas stations, to the extent that DEA even knows of them, have routinely demonstrated a reckless disregard of the spirit of the CMEA quantitative sales limits, by not monitoring sales to individuals either in a single day or during the 30-day period. It has been observed that on a regular basis, the same individual or individuals made multiple package purchases that exceeded the single day sales and/or 30-day purchase limits, without denial by the outlet.

DEA has obtained anecdotal evidence in some investigations that the owners or employees of convenience stores suspected that purchasers of List I products were diverting these products to the clandestine manufacture of methamphetamine. Whether a retail seller or a distributor intentionally diverts scheduled listed chemical products or unwittingly sells such products that are ultimately diverted, DEA must take steps to protect the public from clandestinely manufactured methamphetamine.

25. Does DEA have a long term strategy to eliminate all sources of List 1 chemicals from the marketplace?

RESPONSE:

No such strategy exists. Moreover, DEA would not deny the legitimate needs of these chemicals from the public. It is, however, DEA's Congressional mandate to protect the public from those who would divert controlled substances and listed chemicals from legitimate channels for non-legitimate purposes.

26. As a follow up to Dr. Heiden's testimony that most products found in small toxic laboratories were named brand products rather than off-brand products, Mr. Rannazzisi responded by saying that off brand products were, in fact, being found in large quantities. There seems to be a disparity in these two answers. The Subcommittee would like to clear this up, and, for this reason, would like the DEA to provide documentation showing that after the enactment of CMEA, there has been a consistently greater presence of brands sold in small retail outlets versus name brand or so-called "conventional" retail braud generics during clandestine lab seizures.

RESPONSE:

The question mischaracterizes Mr. Rannazzisi's testimony. At no point in his remarks did Mr. Rannazzisi say that name brand products were not being found in methamphetamine laboratories, nor did he characterize quantities of off-brand products as being large, he simply identified by name those gray market products which were found in laboratories.

In responding to Mr. Heiden's testimony on this issue, Mr. Rannazzisi said:

> "Now, I noticed in Mr. Heiden's testimony, he says the products distributed by ACRC and other small distributors are off-brand combination ephedrine asthma relieve products which are not found in illicit labs as precursors to make methamphetamine. That is incorrect.
>
> In 2006, we had 87 labs with brand names like BDI, Blue Label, Mini Thins, Bronchis, Mini Ephedrine, Double Action Ephedrine, Rapid Ephedrine, Fred's Private Label, Ephedrine Extra, Biotech, AM BC Powder, Ultra Max Strength. Those are all off-brand, gray market crypto-generic products."

Dr. Heiden suggests that he has data on all small toxic laboratories in support of his saying that the name brand products are found more often than off-brand products. Often law enforcement does not know the source of the products found in clandestine labs because the lab operators have discarded or destroyed the packaging materials. Additionally, the quality of the reporting of seized material labeling by various agencies is inconsistent. Mr. Rannazzisi simply stated that off-brand products were found in large quantities. Off-brand manufacturer and distributor data, particularly with respect to ephedrine products, suggests that off-brands would likely be found in clandestine labs.

The attached charts show 92 clandestine meth lab seizures where it is known that ephedrine products were being used in the manufacturing process. During the same time period, 7,345 labs were seized. As in years prior to the enactment of the CMEA, traffickers continue to go to great lengths to disguise the identity of the precursor products from law enforcement. However, intelligence information from all law enforcement sources indicates that ephedrine products, especially those products sold in small retail outlets, are favored by traffickers. (See attachments below.)

27. Dr. Heiden devoted a considerable amount of his testimony challenging the DEA's use of outside data in formulating an annual needs assessment for the importation of Ephedrine. The only response to Dr. Heiden's testimony Mr. Rannazzisi made was that the DEA is reviewing comments and would be out with a revised assessment shortly. Before the DEA issues its final needs assessment, and completes the Interim Final Rule that it issued two days before the hearing, the Subcommittee would appreciate DEA providing the following:

a. **The amount of raw materials known to be diverted in prior years versus the quantity of raw materials on approved LONOs for that same year for all importers and manufacturers. (*See footnote below)***

RESPONSE:

The amount of diverted List 1 raw materials is unknown. Therefore, a direct correlative relationship is meaningless. Annually, the DEA receives an average of about 500 requests per year for LONOs. A LONO was issued in approximately 95% of the cases. In the balance of the cases, fewer than 5%, the request was withdrawn after DEA made notification to the importer that a LONO would not be issued because of diversion concerns.

b. **What is DEA's justification for its *initial* quota policy causing additional "anticipate[d] significant economic impact" on small businesses when the CMEA has already effectuated a major decline in diversion rates? (See pg.37445, FR DOC E7-13377)**

RESPONSE:

Legitimate small businesses should not expect to experience such an impact. The Office of Chief Counsel, Diversion & Regulatory Litigation Section (CCD) engaged the services of a marketing expert. Since 2000, the Office of Diversion Control (OD) and CCD have used market studies which support DEA's position regarding these products. According to the expert, who has testified in court and at show cause proceedings in which the government prevailed, these products are being distributed in quantities far in excess of their expected market share. In other words, they sell more than the nationally recognized brand, yet do not even register as a competitor in the same marketplace as the nationally recognized brand leader. This can only be because their products are aimed at the illicit market.

28. **In his testimony, Mr. Rannazzisi made specific reference to the success of the CMEA in reducing the diversion of over the counter products (OTC) to small toxic laboratories to produce methamphetamine. He stated, however, that the agency continues to be concerned with the contribution of products sold to convenience stores tied to the meth problem. In light of these assertions, the Subcommittee would like the agency to provide the subcommittee with specific evidence demonstrating the extent to which reduction of diverted OTC products is attributable to the CMEA compliance of the distributors and employees of what DEA deems to be "conventional outlets"(drug stores, grocery stores, discount department stores, superstores, and electronic mail order houses)? (See pg.37445, FR DOC E7-13377).**

RESPONSE:

Even prior to the enactment of the CMEA, well before September 30, 2006, a number of traditional ("conventional") outlets engaged in voluntary measures to curtail potential diversion

of pseudoephedrine and or/ephedrine-containing drug products by instituting point of purchase sales limits, and placing ephedrine and pseudoephedrine-containing drug products behind the counter.

Bayer Corporation and Wyeth, manufacturers of Bronchaid and Primatene, respectively, the only two ephedrine-containing brand name products sold in the marketplace at traditional outlets, have long considered these products as fading away, in that sales of these products continue to decrease year by year. Other manufacturers have abandoned using ephedrine altogether and reformulated products with phenylephrine. Phenylephrine cannot be used successfully in the illicit manufacture of methamphetamine.

a. If the DEA dubbed, "non-conventional outlets" contributed to the majority of diverted OTC products, then how can these same businesses be denied recognition for the significant decline in the seizures of Clandestine Methamphetamine Labs?

RESPONSE:

The concern lies with the training of employees for the self certification process and the greater oversight given to employees in conventional outlets versus non-conventional outlets. DEA has sent individuals into convenience stores to gather information on the record keeping process to determine if the log book requirements were being followed. On the whole, clerks in the convenience stores did not check identification against what was written in the log books while the larger more conventional outlets did in fact check the identification against what was written in the log books.

Despite the logbook requirement, "smurfing" (going from store to store and purchasing the maximum daily limit) continues because there is no apparatus for stores to compare logbooks.

b. In light of the dramatic and undeniable effects of the CMEA's regulations on the reduction of diverted OTC products containing PSE and EPH; why is DEA policy *still* contradicting the CMEA, by effectively banning the convenience store industry and its consumer's access to these products?

RESPONSE:

DEA policy does not contradict the CMEA and it is not DEA's intent to ban the convenience store industry from access to these products.

*** Footnote: CLSS (Clandestine Laboratory Seizure System @ EPIC) has the statistics available that would reveal how many pounds of methamphetamine were illicitly manufactured in 2006* from products diverted via all retail outlets.** That amount (number of pounds of methamphetamine) can then be converted into the kilograms of raw materials required to produce that amount. Next, calculate the kilograms of raw materials that were approved for import that year for the**

manufacture of ALL OTC products containing PSE and EPH. Subtract the estimated diverted kilograms from the amount that was actually imported, and you should end up with an importation level that reflects the amount of raw materials that were not diverted, and that is the amount that should be approved for the following year Not an amount based loosely on estimates of how many cold, allergy and asthma suffers there are and where they shop.

*** In 2006, when CMEA was enacted, not all retail regulations were in effect until September.**

****For 2004, CLSS reported that 3,156 lbs of Methamphetamine was illicitly manufactured from products diverted from all retail/wholesale outlets. (During that year, lab seizures were approximately 700% greater than annualized data currently available for 2007, and 230% greater than 2006 data.)**

RESPONSE:

For the record, this footnote is incorrect to state that "For 2004, CLSS reported that 3,156 lbs of Methamphetamine was illicitly manufactured from products diverted from all retail/wholesale outlets."

In 2004 there were 17,860 meth lab incidents (labs, dumpsites). In most, if not all these incidents, ephedrine/pseudoephedrine tablets were used to manufacture methamphetamine. Just because the brand cannot be determined, does not mean that these tablets were not used, and therefore, no statement can be made that only 3,156 lbs of methamphetamine was manufactured from ALL retail/wholesale outlets.

In the vast majority of clandestine laboratories, it is difficult for law enforcement to determine the name brand of ephedrine/pseudoephedrine tablets, gel-caps or liquids that have been used. In most instances, the law enforcement officers may only find materials that have already been removed from the packaging therefore making it impossible to determine the brand. List 1 materials found in solutions obviously would make source determination improbable. Due to these conditions, there may be inherent under-reporting or mis-reporting considerations. Therefore, no system exists for making a reliable empirical determination of the amount of methamphetamine resulting from specific retail and wholesale products' diversion.

Again, DEA has engaged an expert in the field of retail marketing and statistics who has studied purchases of drug products containing ephedrine and pseudoephedrine at the convenience store level. In his studies he has concluded that retailers purchase these products in amounts that are far in excess of legitimate need when comparing the purchases to demographics, census data, and statistical sales data obtained from the convenience store industry.

Cases in Which Administrative Law Judge's Opinion Issued
January 1, 2001 - July 26, 2007
(Revised August 1, 2007)

*Arranged according to the date the Judge's opinion is rendered.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
01-4	Peterson	11/16/00	1/12/01	2/12/01	10/10/01	
00-12	Ford	12/9/99	2/6/01	3/16/01	2/24/03	
99-34	Shaffer	9/17/99	3/27/01	4/30/01	5/6/02	
01-1	The Church of the Living Tree	11/30/99	4/17/01	6/12/01	3/26/03	
01-17	Thomassen	3/9/01	4/23/01	5/24/01	10/10/01	
00-4	Owens	11/1/99	5/4/01	6/4/01	7/24/02	
01-18	Resnick	3/22/01	5/16/01	6/18/01	10/10/01	
00-24	Leslie	6/20/00	8/2/01	9/14/01	3/6/03	
01-6	Scolaro	11/22/00	8/3/01	9/7/01	6/11/02	
01-37	Anthony	8/6/01	10/3/01	11/20/01	5/6/02	
01-38	Weinstein	8/7/01	10/3/01	11/19/01	5/6/02	
01-36	Venuto	8/6/01	10/3/01	11/19/01	5/6/02	
00-41	Mediplas Innovations	9/15/00	10/4/01	11/20/01	5/30/02	
01-43	Mills	8/20/01	1/8/02	2/12/02	5/6/02	
02-1	Deanwood Pharmacy	10/12/01	3/7/02	10/29/02	6/23/03	
01-22	Xtreme	5/4/01	4/3/02	5/7/02	12/2/02	
01-12	Indace[1]	2/8/01	4/5/02	6/5/02	12/13/02 & 11/9/04	
01-13	Malladi[2]	2/8/01	4/5/02	6/5/02	12/13/02 & 11/9/04	
02-17	Washburn	1/25/02	4/25/02	6/4/02	9/12/02	

[1] The United States Court of Appeals for the District of Columbia Circuit remanded both *Indace* and *Malladi* to the Deputy Administrator, necessitating second final orders in both cases. See 69 Fed. Reg. 67,951 (2004).
[2] See fn. 1.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
02-34	Arwas	3/21/02	4/29/02	5/29/02	9/18/02	
01-3	Penick Corp.	11/15/00	5/29/02	8/5/02	1/29/03	
02-38	Graves	4/29/02	6/10/02	7/10/02	11/4/02	
01-30	Jackson	7/2/01	6/13/02	7/17/02	4/21/03	
02-15	Genesis	1/22/02	6/26/02	8/8/02	3/13/03	
02-37	Hamilton	4/22/02	7/9/02	8/8/02	9/18/02	
02-25	Talley	2/26/02	7/15/02	8/21/02	11/20/02	
02-41	Cleggett-Lucas	5/17/02	7/13/02	10/29/02	4/21/03	
00-22	OTC	6/9/00	8/8/02	9/27/02	11/26/03	
02-44	Santucci	6/14/02	8/12/02	9/18/02	10/28/02	
01-20	Aboumahboub	4/17/02	8/15/02	9/18/02		Terminated[3] – Joint Motion filed 12/6/04
02-46	Meredith	6/26/02[4]	9/13/02	10/24/02	07/31/2003[5]	Published 8/1/03
02-50	Serai	7/23/02	9/18/02	10/28/02	7/28/03	
02-52	Goswitz	7/24/02	10/8/02	11/12/02	4/21/03	

[3] The administrative law judge will terminate a case either because (1) it has become moot (e.g., the respondent's registration expired during the course of the proceedings and the respondent did not file a renewal application); (2) the parties settle all outstanding issues; or (3) the respondent failed to comply with a directive from the judge and was therefore deemed to have waived his right to a hearing. If a case is terminated for the first or second reason listed above, no further action is required by either this office or the Deputy Administrator; if a case is terminated for the third reason, the investigative file should be forwarded to the Deputy Administrator for issuance of a final order based on that file. A case may also become moot or may be settled while pending before the Deputy Administrator, in which case it will be terminated.

[4] On June 26, 2002, the hearing clerk received a letter from respondent in which he "requests an extension of time re: his show cause hearing until the registrants [sic] federal complaint is adjudicated." This letter was listed as a request for an extension of time to respond to the order to show cause on the docket sheet, but was treated as a request for hearing.

[5] This date represents when the document was filed at the Federal Register. The date the Final Order was signed is unknown.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
01-15	Ashland	3/1/01	10/28/02			Terminated11/17/06[6]
01-23	FCC	3/1/01	10/28/02			Terminated 11/17/06[7]
02-11	Davis	12/13/01	11/21/02	1/21/03	12/18/03	
01-10	Branex	1/26/01	12/4/02	1/21/03	2/10/04	
03-4	Dinozzi	10/21/02	1/13/03	2/19/03	11/13/03	
03-2	Lusman	10/9/02	1/13/03	2/20/03	11/13/03	
03-9	Perry	11/26/02	2/25/03	3/18/03	11/13/03	
03-14	Prescriptionline.com	1/22/03	3/19/03	4/22/03	1/7/04	
02-24	Kruger	4/9/02	4/23/03	5/28/03	1/20/04	
02-10	Morall	12/17/01	4/28/03	7/24/03	9/28/04	
02-7	Davenport	12/10/01	6/13/03	8/6/03	11/26/03	
02-35	Chaudry	3/25/02	6/13/03	8/6/03	10/5/04	
03-27	Edwin	5/22/03	7/18/03	8/20/03	9/13/04	
03-19	Katz	4/28/03	8/8/03	9/12/03	3/29/04	
03-22	Boone	4/28/03	8/29/03	11/24/03	5/17/04	
03-36	Antonsson	Unknown[8]	9/23/03	11/13/03	1/7/04	
03-41	Ingram	8/18/03	11/7/03	12/15/03	4/7/04	
02-40	Hale	5/13/03	11/26/03	1/15/04	11/10/04	
03-51	Jones	9/23/03	12/4/03	1/16/04	6/21/04	
03-48	Strauss	9/11/03	12/8/03	1/16/04	5/17/04	

[6] At the Government's request, *Ashland* and *FCC* were ultimately terminated without being submitted to the Deputy Administrator. These cases were part of a series of proceedings (including *Indace* and *Malladi*) involving PDK Laboratories, Inc.

[7] See fn. 5.

[8] The respondent (Antonsson) requested an extension of time to respond to the Order to Show Cause on July 5, 2003. No formal hearing request was received. On July 29, 2003, the Government requested for a Stay of Proceedings and Motion for Summary Disposition. The Opinion and Recommended decision of the ALJ was made on September 23, 2003.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
04-10	RX Network of South Florida, LLC	11/5/03	12/17/03	1/29/04	10/5/04	
04-7	Pripstein	10/15/03	12/19/03	1/28/04		Terminated 8/17/05
02-28	Prakasam	3/6/02	1/30/04	3/2/04	5/25/05	
04-9	Orzame	11/10/03	2/4/04	3/15/04	9/8/04	
03-1	Hoxie	10/4/02	4/7/04	5/26/04	7/27/04	
01-31	Bordeaux	7/3/01	5/4/04	6/7/04	11/10/04	
03-5	Express Wholesale	11/8/02	5/18/04	6/24/04	10/5/04	
04-2	Yaqub	10/6/03	5/14/04			Terminated 7/12/04
04-22	Townsend	5/10/04	6/28/04			Terminated 11/15/04
04-34	Price	5/3/04	6/28/04	8/10/04	10/5/04	
04-38	Chalifoux	5/12/04	6/28/04	8/10/04	10/5/04	
04-40	Mirza	5/17/04	8/10/04	9/15/04	10/5/04	
03-35	Joy's Ideas	8/26/03	9/29/04	11/8/04	5/25/05	
03-25	Elk Int'l, Inc.	5/14/03	10/7/04	11/16/04	5/2/05	
04-27	Bradway	4/5/04	10/15/04			Terminated 11/16/04
04-30	Gooberman	4/13/04	10/15/04		5/9/05	
04-63	Siddall	8/16/04	11/4/04	12/7/04	12/15/05	
05-1	Rygiel	Unknown[9]	11/22/04	1/11/05	5/9/05	
03-24	TNT Distributors, Inc.	4/28/03	12/3/04	1/11/05	2/14/05	
03-26	H&R Corp.	5/20/03	12/3/04	1/11/05	5/5/06	
04-62	Kobrin	7/28/04	12/27/04	2/2/05	5/25/05	
05-5	Goodrich	11/8/04	12/29/04	2/2/05	5/2/05	

[9] No formal request for hearing was received. The Respondent requested for an extension of time to respond to the Order to Show Cause.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
03-81	Nearing	3/10/03	1/3/05	2/2/05	5/25/05	
01-45	Chattem Chemicals, Inc.	9/7/01	2/16/05	6/6/05	2/17/06	
03-39	D&S Sales	7/21/03	2/11/05	3/22/05	6/12/06	
05-9	Rodriguez	11/17/04	2/16/05	3/22/05	5/25/05	
04-8	Wedgewood Village Pharmacy	10/16/03	3/4/05	5/17/05	3/22/06	
05-2	Bergman	10/29/04	3/8/05	4/14/05	5/25/05	
05-17	Graham	1/6/05	3/25/05	4/26/05	5/25/05	
02-47	Kennedy	7/15/02	4/13/05	6/14/05	6/12/06	
03-8	Krishna-Iyer	11/20/02	4/15/05	7/27/05	8/22/06	
05-7	Yeates	11/10/04	5/9/05	6/14/05	6/13/06	
05-15	Oakland Medical Pharmacy	12/13/04	5/27/05	8/17/05	8/15/06	
05-28	The Medicine Shoppe	5/6/05	6/29/05	8/2/05	7/20/06	
05-27	Michael's Discount Pharmacy	5/6/05	7/1/05	8/2/05	8/15/06	
04-4	Tri-County Distributors	10/8/03	7/6/05	8/9/05	8/22/06	
02-9 & 02-43	Chein	12/13/01	7/28/05	12/23/05	1/19/07	
05-36	Dilday	8/3/05	9/23/05	10/26/05	8/22/06	
04-16	T. Young Associates, Inc.	1/20/04	10/28/05	11/30/05	9/14/06	
03-12	Koller	12/26/02	11/15/05	12/21/05	11/3/06	
04-48	Lockridge	6/14/04	11/18/05	12/23/05	12/8/06	
04-68	Mitrione	9/2/04	3/2/06	4/12/06		Terminated 3/30/07 by Deputy Administrator

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-42	Champaign Urbana Public Health District	1/29/05	3/7/06	5/22/06		No Final Order Issued[10]
02-6	Houba	11/20/01	3/8/06	6/5/06		Terminated 3/30/07 by Deputy Administrator
06-39	Dariah	11/16/05	4/17/06	06/1/06	1/19/07	
05-26	Tank Wholesale	4/19/05	4/24/06	6/1/06		Pending Final Order
05-22	Planet Trading, Inc. d/b/a United Wholesale Distributors, Inc.	3/24/05	4/25/06	6/5/06	2/28/07	
04-41	Jackson	5/18/04	5/26/06	6/29/06	4/24/07	
03-21	Medicine Shoppe Jonesborough	4/18/03	6/9/06	7/14/06		Remanded 4/28/07
05-8	Rick's Picks, L.L.C.	11/15/04	8/9/06	9/22/06	3/30/07	
06-52	Green Acres, Farm, Inc.	3/14/06	8/9/06	9/18/06	4/25/07	
06-58	Patel	6/19/06	8/28/06	10/2/06	3/30/07	
06-46	Miciano	2/27/06	8/28/06			Terminated 10/27/06
04-36	Lewis	5/4/04	9/26/06	11/2/2006	1/19/07	
06-68	Bourne Pharmacy	8/29/06	11/6/06	12/11/06	3/30/07	
05-24	The Lawsons Inc., t/a The Medicine Shoppe	5/13/05	11/6/06	3/14/07		Pending Final Order
04-58	RX Direct Pharmacy, Inc.	6/22/04	11/21/06	1/17/07		Pending Final Order

[10] A final order was prepared but it was not published in the Federal Register because the case became moot.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-4	Trinity Healthcare Corp., d/b/a Oviedo Discount Pharmacy	9/23/05	10/2/06	11/13/06	5/21/07	
05-3	Fotinopoulos	11/1/04	10/11/06	11/15/06	4/25/07	
05-33	Holloway Distributing, Inc.	6/30/05	12/19/06	2/1/07		Pending Final Order
07-3	Elite Pharmacy	11/1/06	1/23/07	2/15/07		Terminated on 4/3/07
05-16	Craker	2/7/05	2/12/07	5/15/07		Pending Final Order
05-24	The Lawsons, Inc., t/a/ The Medicine Shoppe Pharmacy	5/13/05	2/12/07 Supplemental [11]	3/14/07		Pending Final Order
07-19	CRJ Pharmacy, Inc. & YPM Total Care Pharmacy, Inc.	3/2/07	3/22/07	4/19/07	5/21/07	
07-7	Southwood Pharmaceuticals, Inc.	1/3/07	3/30/07	5/8/07	6/22/07	
07-23	Newcare Home Health Services	3/12/07	4/3/07	5/4/07		Pending Final Order

[11] Pursuant to the November 6 issuance of the ALJ's Opinion and Recommended Ruling, an exception to this opinion was filed on November 26 and Counsel for the Respondent filed a motion for reconsideration. This Motion was granted, however neither party filed briefs. Consequently, a Supplemental Opinion and Recommended Ruling were issued.

Docket No.	Case Name	Request for Hearing Date	Date Judge's Opinion Issued	Date Sent to Deputy Administrator	Date of Deputy Administrator's Final Order	Comments
06-19 & 06-20	Saran	10/20/05	4/30/07			Pending Parties Exceptions, then to Deputy Administrator[12]
07-18	Wood	2/21/07	4/27/07	6/4/07		Pending Final Order
07-21	United Prescription Services, Inc.	3/6/07	5/31/07	6/26/07		Pending Final Order
06-45	Volkman	6/20/07	6/20/07			Pending Parties Exceptions, then to Deputy Administrator
05-38	Memphis Wholesale Company	8/18/05	6/20/07	7/23/07		Pending Final Order

[12] At respondent's request, the judge granted an extension until October 1, 2007, for the filing of exceptions. The exceptions will then be transmitted to the Office of the Deputy Administrator.